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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,325	09/12/2005	Kevin Woehr	54104/THD/K163	5105
23363	7590	05/29/2007	EXAMINER	
CHRISTIE, PARKER & HALE, LLP			BRITTINGHAM, JOHN M	
PO BOX 7068			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/520,325	WOEHR, KEVIN	
	<b>Examiner</b>	<b>Art Unit</b>	
	John M. Brittingham	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 January 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 1/4/2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/4/2005; 12/12/2005.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: IDS 2/9/2007.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woehr et al (USPN 6,117,108) in view of Rogers et al. (USPN 5,405,323). Woehr ('108) discloses a safety intravenous (IV) catheter insertion device.

4. In regards to claims 1, 4, 7, and 9 Woehr ('108) discloses a catheter insertion device (10) comprising a hollow-cylindrical catheter hub (26), catheter tube (24), needle hub(12), a hollow needle (16), a needle guard element (40) on the needle within the catheter hub (36) and an engaging section for the needle guard element which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter ( col. 5, lines 22-46), a radial projection (68) projecting radially from the inner circumference of the catheter hub (26),

which is configured to engage with the needle guard element in the ready position (figure 4A) and an inner circumference with a radial projection (62) for positioning the needle guard element. A needle guard element (120) formed as a spring clip (figures 10A, 10B, 11A and 11B) which has diametrically opposite spring arms (122 and 124) starting from a rear wall provided with a bore (134), wherein bent end sections of the spring arms overlap and block the needle tip when the engaging means (138) of the needle comes to abut on the rear wall (figure 10B). However, Woehr lacks a check valve disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle. Rogers ('323) discloses a check valve (10) disposed between the catheter tube (16) and the needle guard element (26 and 33) in the catheter hub (13) through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (figures 1 and 2 and Col. 3, lines 30-55 and Col. 4, lines 23-62). Since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle.

5. Woehr ('278) discloses all the limitations of claim 1 in addition to a catheter hub (26) having a distal hub element (28) and a proximal hub element (30). However, concerning claim 2, Woehr lacks a check valve held between a distal hub element and a proximal hub element which are joined to one another. Rogers ('323) discloses a check valve (10) held between a distal hub element (55) and a proximal hub element (53) which are joined to one another (figure 2). The

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purpose of the check valve is to control fluid transmission in or out of the body vessel after the catheter has been placed. It would have been obvious to one of ordinary skill in the art to modify Woehr's cathter insertion device with a check valve positioned between a distal hub element and a proximal hub element of a catheter hub to control fluid transmission from a catheter.

6. Woehr ('108) discloses the limitations of claim 1. However, concerning claim 3, Woehr lacks a check valve with a plurality of radially elastically expandable valve flaps configured to be moved into an open position by fluid pressure generated from a syringe. Rogers ('323) discloses a check valve (10) with two valve flaps ( figure 2 nad 9) configured to be moved to an open position by fluid pressure from a syringe ( col. 4, lines 45-55). It is known in the art that check valves can have multiple flaps to control fluid transmission such that it would have been obvious to one of ordinary skill in the art to modify Woehr's cathter insertion device with a check valve configured to be moved to an open position by fluid pressure control fluid transmission.

7. Woehr ('108) teaches the limitations of claim 1. However, concerning claims 5 and 6, Woehr lacks a check valve with valve disc, which has radial slits starting from a middle section of the valve disc and a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element, and an actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section. Rogers ('323) discloses a check valve comprised of a valve disc (51), radial slit (48), and a valve actuating element (12) displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element (34), and an actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section Figure 2 and Col. 4, lines 23-62). Check valves are well known in the art have

been comprised of valve discs, radial slits and an actuating element such that it would be obvious to one of ordinary skill in the art to modify Woehr with Rogers to include a check valve that controls intravenous fluid delivery.

8. Woehr ('108) teaches the limitations of claims 1, and 5. However, concerning claim 8, Woehr lacks a valve actuating element having a truncated cone-shaped abutting section. Rogers ('323) discloses a valve actuating element having a truncated cone-shaped abutting section (12) (figure 2).

9. In regards to claims 10 and 11, Woehr ('108) teaches a catheter tube (24) attached to an end of a catheter hub (26), the catheter tube comprising a lumen and the catheter hub comprising an interior cavity (figure 1A); a needle (16) defining a needle axis attached to an end of a needle hub (12), projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip(60 and figures 1A –1D). A needle guard element (120) comprising two needle guard arms (122 and 124) crossing the needle axis of the needle positioned inside the catheter hub (figure 10A) and an opening (134) adapted to contact the engaging section of the needle (figure 10B). Woehr lacks a check valve positioned adjacent to the catheter hub and between the catheter hub and the needle hub. Rogers ('323) discloses a check valve (10) positioned adjacent to the catheter hub (11) and between the catheter hub and the needle hub (18). IV catheters have been well known in the art as a means to control fluid transmission into a patient and out of a patient, it would have been obvious to one of ordinary skill in the art to modify Woehr's ('108) safety IV catheter Rogers' ('323) catheter check valve assembly by positioning the check valve between the catheter hub and the needle hub in order to control fluid transmission after a catheter had been placed in a patient's vessel and the needle removed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Brittingham whose telephone number is 571-270-1891. The examiner can normally be reached on M-TH 0730-1700, 1st FRI off, 2nd FRI 0830-1700 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John Brittingham  
JMB  
3/26/2007

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